March 24, 2005

Misty L. Bogle
Senior Product Manager
Reilly Industries, Inc.
300 North Meridian Street
Suite 1500
Indianapolis, IN 46204

Dear Ms. Bogle:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-Vinylpyridine posted on the ChemRTK HPV Challenge Program Web site on March 3, 2004. I commend Reilly Industries, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Reilly Industries advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/S/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
2-Vinylpyridine

Summary of EPA Comments

The sponsor, Reilly Industries, Inc., submitted a test plan and robust summaries to EPA for 2-Vinyl-pyridine, CAS No. 100-69-6, dated December 30, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on March 3, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

2. Environmental Fate. The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

3. Health Effects. The submitted data for acute, repeated-dose, and genetic toxicity endpoints are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan to conduct a combined reproductive/developmental toxicity screening test; the results, together with reproductive toxicity data from the existing 90-day repeated-dose toxicity study, will satisfy the reproductive toxicity endpoint. The submitter needs to address deficiencies in the robust summaries.

4. Ecological Effects. EPA agrees with the submitter's proposal to conduct testing of 2-vinylpyridine in fish, daphnia and algae to satisfy these endpoints.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 2-Vinylpyridine Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitted data for acute, repeated-dose, and genetic toxicity endpoints are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan to conduct a combined reproductive/developmental toxicity screening assay following OECD TG 421. The submitter needs to address some deficiencies in the robust summaries.

Reproductive toxicity. The submitter provided data on reproductive organs from an existing 90-day repeated-dose toxicity study; however, no existing adequate developmental toxicity study is available.

While the submitter's statement that "The reproductive endpoint is fulfilled by the complete histological examination of reproductive organs from the 90-day study" is incorrect, EPA agrees that the observation of no effects on reproductive organs in the 90-day repeated-dose study, together with the proposed combined reproduction/developmental toxicity screening assay, will adequately address the reproductive toxicity endpoint for the purposes of the HPV Challenge Program. The reproductive toxicity robust summary will need to be updated with information from the combined reproductive/developmental toxicity screening study.

Developmental toxicity. No data are provided. EPA agrees with the submitter's proposed combined reproductive/developmental toxicity screening test (OECD TG 421) to address this endpoint.

In addition, the submitter needs to revise the reproductive toxicity row in the "Data Availability Summary Table" on page 2, as the full data for this endpoint are not available (change "Y" to "N") and testing is needed (change "N" to "Y" and add OECD TG 421 (oral) in the "Notes" column).

Ecological Effects (fish, invertebrates, and algae)

EPA agrees with the submitter's proposal to conduct acute testing of 2-vinylpyridine in fish (OECD TG 203), daphnia (OECD TG 202), and algae (OECD TG 201) to satisfy these endpoints.

Specific Comments on the Robust Summaries

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Genetic toxicity. The robust summary for the in vitro reverse mutation assay in four strains of *Salmonella typhimurium* and one strain of *Escherichia coli* is missing details including culture conditions, duration of incubation, individual test concentrations, concentration-response data, criteria for a positive response, response information on positive controls, and the statistical methods and analyses. The robust summary for the *in vitro* chromosomal aberrations assay in Chinese hamster adenofibroblast cells is missing details including culture conditions, the use and concentration (or absence) of a metaphase-arresting substance, duration of cell exposure, response from positive controls, type of aberrations observed in treated and control cultures, criteria for scoring aberrations, and the results of statistical analyses.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.